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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/524,382 | 09/30/2005 | Phillip Neil Shaw | 35365.4 | 4708 |

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HAYNES AND BOONE, LLP

IP Section

2323 Victory Avenue

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EXAMINER

SASAKI, SHOGO

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

06/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/524,382 | | SHAW ET AL. | |
| | Examiner | | Art Unit | |
| | Shogo Sasaki | | 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/28/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-19, 26-32 and 54-59 is/are pending in the application.
- 4a) Of the above claim(s) 11-19, 26-32, 55, 56 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10, 54, 57 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/14/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/14/05, 4/11/05, 4/10/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendments to claims are acknowledged. Cancellation of claims 8, 20-25 and 33-53 is also acknowledged.

Election/Restrictions

2. Applicant's election of Group I in the reply filed on 4/10/2009 is acknowledged.
3. Applicant's arguments in view amendments to the claims filed 4/10/2009 and 4/28/2009 have been fully considered.

The newly presented Group I still does not offer contribution over the prior art (See rejections below). Thus there still exists lack of unity *a posteriori*. The original restriction requirement is still deemed proper, and is made FINAL. Claims 11-19, 26-32, 55, 56 and 58 are withdrawn from consideration.

Claims

4. Regarding claims 1, 4-6, 57 and 59, recitations [claim 1] "for supplying a diluted sample to a mass spectrometric analyzer," "arranged to mix a sample with a diluent to form the diluted sample," "such that, in use, a sample enters the mixer through the first conduit at a first flow rate and a diluent enters the mixer through the second conduit at a second flow rate, the mixer being arranged so that said diluted sample exits the mixer through a third conduit at a third flow rate, said third flow rate being substantially equal to the sum of the first and second flow rates" and "arranged to control the first or second flow rate respectively;" [claim 4] "wherein a dilution factor by which the sample is diluted is calculable from the ratio of the first and second flow rates;" [claim 5] "a dilution factor by which the sample is diluted is calculable by comparing the detected amount of said internal standard by the analyzer with the amount of internal standard in the sample or diluent;" [claim 6] entire recitation; [claim 57] "for supplying a diluted sample to a mass spectrometric analyzer," "for mixing a sample with a diluent," "supplying a sample to the mixer at a first flow rate," "for supplying a diluent to the mixer at a second flow rate," "for receiving a diluted sample from the mixer," "for pumping the diluted sample from the

mixer to a mass spectrometric analyzer at a third flow rate substantially equal to the sum of the first and second flow rates” and “for controlling the first or second flow rate, respectively;” and [claim 59] “wherein the initial dilution factor is 100,” which are directed to the manner in which a claimed apparatus is intended to be used do not distinguish the claimed apparatus from the prior art.

5. It is noted that claim 1 does not positively claim: (a) a first conduit; (b) a second conduit; (c) a third conduit; (d) an analyzer; (e) a valve or variable constriction; (f) a sample; (g) a diluent; and (h) a diluted sample. Therefore, they were not considered to be structurally limiting. Any further references to said elements were not given patentable weight even if those references further limit said unclaimed element.

6. It is also noted that claim 57 does not positively claim: (a) an analyzer; (b) a sample; (c) a diluent; and (d) a diluted sample.

7. Claim 10 is objected to because of the following informalities: Regarding claim 10, the mass spectrometer in preamble is not accorded any patentable weight. The recitation does not add said structural element to the device being claimed. An invention is defined by the listing of elements which follows the transitional phrase. Claim 10 recites same invention as recited in claim 1, and fails to further limit the subject matter. Claim 10 as currently presented needs to be cancelled.

Note: The disclosure states that applicant’s invention may be used with a mass spectrometer (which is not applicant’s invention). The use of applicant’s pumping device with a mass spectrometer appears to be an intended use of applicant’s invention.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-7, 9, 10, 54, 57 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, it is unclear if applicant intends to positively set forth: (a) a first conduit; (b) a second conduit; (c) a third conduit; (d) an analyzer; (e) a valve or variable constriction; (f) a sample; (g) a diluent; and (h) a diluted sample, as part of the claimed subject matter.

Also regarding claim 1, it is unclear what is meant by the recitation “a controller arranged to...” It is unclear if the recitation specifies: (a) a specific special/positional arrangement of the controller with respect to the other components of the device; or (b) a specific computer program/software (which does not appear to be described in the specification) within the controller performing specific tasks.

Claim 10 include the element “mass spectrometer” which is not described in the specification as being a structurally limiting element of claim 1 or claim 10. Therefore said element renders claim 10 indefinite.

Regarding claim 57, it is unclear if applicant intends to positively set forth: (a) an analyzer; (b) a sample; (c) a diluent; and (d) a diluted sample, as part of the claimed subject matter.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-7, 9, 10, 54, 57 and 59 are rejected under 35 U.S.C. 102 as being unpatentable over by the Applicant's Admission of Prior Art (Fig. 2; and [0010]-[0019]).

Regarding claims 1-7, 9, 10, 54, 57 and 59, the Applicant's Admission of Prior Art (AAPA) discloses a pumping device comprising: **[A]** a mixer (34), a controllable ([0015]) pump (31) and a pump controller (The controller will have to be provided for controlling the controllable pump 31); and **[B]** a mixer (34); a first conduit (33 or 33'); a second conduit (35); and a third conduit (30) comprising a pump (31) disposed thereon wherein one of the first and second conduits comprises a valve (32) disposed therein.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shogo Sasaki whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SS

5/27/09

/Brian R Gordon/

Primary Examiner, Art Unit 1797